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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,401	02/19/2004	Philip Ashton-Rickardt	ARCD:390US	4307

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FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER	
FETTEROLF, BRANDON J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,401	ASHTON-RICKARDT, PHILIP	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1 are subject to restriction and/or election requirement.
See Continuation Sheet

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-6,12-17,21-23,25-31,33,35-37,39,40,46,49-52,56,59,61,63,64,91,188-193 and 199-201.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 12-32 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide, wherein the cell is a human patient with an infection, classified in class 514, subclass 2.

II. Claims 1-2, 12-30, 35 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide, wherein the cell is a human patient with septic shock, classified in class 514, subclass 2.

III. Claims 1-2, 12-30, 36-37 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide, wherein the cell is a human patient with hepatic failure, classified in class 514, subclass 2.

IV. Claims 1-2, 12-30, 39-40 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide, wherein the cell is a human patient with an inflammatory disease, classified in class 514, subclass 2.

V. Claims 1-2, 12-30, 46, 49 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide, wherein the cell is a human patient with a vascular disease, classified in class 514, subclass 2.

VI. Claims 1-2, 12-30, 50 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide, wherein the cell is a human patient with cancer, classified in class 514, subclass 2.

VII. Claims 1-2, 12-30, 51-52 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide, wherein the cell is a human patient with a bone disease, classified in class 514, subclass 2.

VIII. Claims 1-2, 12-30, 56 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide, wherein the cell is a human patient with a viral infection, classified in class 514, subclass 2.

IX. Claims 1-2, 12-30, 59 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide, wherein the cell is a human patient with an autoimmune disorder, classified in class 514, subclass 2.

X. Claims 1-2, 12-30, 61 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide, wherein the cell is a human patient with multiple sclerosis, classified in class 514, subclass 2.

XI. Claims 1-2, 12-30, 63-64 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide, wherein the cell is a human patient with arthritis, classified in class 514, subclass 2.

XII. Claims 1, 3-5, 12-30, 31-32 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide equivalent, wherein the cell is a human patient with an infection, classified in class 514, subclass 2.

XIII. Claims 1, 3-5, 12-30, 35 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide equivalent,

wherein the cell is a human patient with septic shock, classified in class 514, subclass 2.

XIV. Claims 1, 3-5, 12-30, 36-37 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide equivalent, wherein the cell is a human patient with hepatic failure, classified in class 514, subclass 2.

XV. Claims 1, 3-5, 12-30, 39-40 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide equivalent, wherein the cell is a human patient with an inflammatory disease, classified in class 514, subclass 2.

XVI. Claims 1, 3-5, 12-30, 46, 49 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide equivalent, wherein the cell is a human patient with a vascular disease, classified in class 514, subclass 2.

XVII. Claims 1, 3-5, 12-30, 50 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide equivalent, wherein the cell is a human patient with cancer, classified in class 514, subclass 2.

XVIII. Claims 1, 3-5, 12-30, 51-52 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide equivalent, wherein the cell is a human patient with a bone disease, classified in class 514, subclass 2.

XIX. Claims 1, 3-5, 12-30, 56 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide equivalent,

wherein the cell is a human patient with a viral infection, classified in class 514, subclass 2.

XX. Claims 1, 3-5, 12-30, 59 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide equivalent, wherein the cell is a human patient with an autoimmune disorder, classified in class 514, subclass 2.

XXI. Claims 1, 3-5, 12-30, 61 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide equivalent, wherein the cell is a human patient with multiple sclerosis, classified in class 514, subclass 2.

XXII. Claims 1, 3-5, 12-30, 63-64 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with an Spi2A polypeptide equivalent, wherein the cell is a human patient with arthritis, classified in class 514, subclass 2.

XXIII. Claims 1, 6, 12-30, 31-32 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with a polypeptide comprising 4 to 8 consecutive amino acid residues of the amino acid sequences MAGVGCCA or FVVAECCM, wherein the cell is a human patient with an infection, classified in class 514, subclass 2.

XXIV. Claims 1, 6, 12-30, 35 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with a polypeptide comprising 4 to 8 consecutive amino acid residues of the amino acid sequences MAGVGCCA or FVVAECCM, wherein the cell is a human patient with septic shock, classified in class 514, subclass 2.

XXV. Claims 1, 6, 12-30, 36-37 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with a polypeptide comprising 4 to 8 consecutive amino acid residues of the amino acid sequences MAGVGCCA or FVVAECCM, wherein the cell is a human patient with hepatic failure, classified in class 514, subclass 2.

XXVI. Claims 1, 6, 12-30, 39-40 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with a polypeptide comprising 4 to 8 consecutive amino acid residues of the amino acid sequences MAGVGCCA or FVVAECCM, wherein the cell is a human patient with an inflammatory disease, classified in class 514, subclass 2.

XXVII. Claims 1, 6, 12-30, 46, 49 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with a polypeptide comprising 4 to 8 consecutive amino acid residues of the amino acid sequences MAGVGCCA or FVVAECCM, wherein the cell is a human patient with a vascular disease, classified in class 514, subclass 2.

XXVIII. Claims 1, 6, 12-30, 50 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with a polypeptide comprising 4 to 8 consecutive amino acid residues of the amino acid sequences MAGVGCCA or FVVAECCM, wherein the cell is a human patient with cancer, classified in class 514, subclass 2.

XXIX. Claims 1, 6, 12-30, 51-52 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with a polypeptide comprising 4 to 8 consecutive amino acid residues of the amino acid sequences MAGVGCCA or FVVAECCM, wherein the cell is a human patient with a bone disease, classified in class 514, subclass 2.

XXX. Claims 1, 6, 12-30, 56 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with a polypeptide comprising 4 to 8 consecutive amino acid residues of the amino acid sequences MAGVGCCA or FVVAECCM, wherein the cell is a human patient with a viral infection, classified in class 514, subclass 2.

XXXI. Claims 1, 6, 12-30, 59 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with a polypeptide comprising 4 to 8 consecutive amino acid residues of the amino acid sequences MAGVGCCA or FVVAECCM, wherein the cell is a human patient with an autoimmune disorder, classified in class 514, subclass 2.

XXXII. Claims 1, 6, 12-30, 61 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with a polypeptide comprising 4 to 8 consecutive amino acid residues of the amino acid sequences MAGVGCCA or FVVAECCM, wherein the cell is a human patient with multiple sclerosis, classified in class 514, subclass 2.

XXXIII. Claims 1, 6, 12-30, 63-64 and 91, as specifically drawn to a method for modulating cell death in a cell comprising contacting said cell with a polypeptide comprising 4 to 8 consecutive amino acid residues of the amino acid sequences MAGVGCCA or FVVAECCM, wherein the cell is a human patient with arthritis, classified in class 514, subclass 2.

XXXIV. Claims 188-191 and 201, as specifically drawn to a method of preparing donor granulocytes for storage, comprising: (a) obtaining donor granulocytes from a suitable donor; (b) isolating said donor granulocytes; (c) contacting said donor granulocytes with a composition comprising an Spi2A polypeptide; and (d) storing said donor granulocytes, classified in class 435, subclass 325.

XXXV. Claims 188-190, 193 and 201, as specifically drawn to a method of preparing donor granulocytes for storage, comprising: (a) obtaining donor granulocytes from a suitable donor; (b) isolating said donor granulocytes; (c) contacting said donor granulocytes with a composition comprising a polypeptide comprising 4 to 8 consecutive amino acid residues of the amino acid sequences MAGVGCCA or FVVAECCM; and (d) storing said donor granulocytes, classified in class 435, subclass 325.

XXXVI. Claims 188-190, 192 and 199-201, as specifically drawn to a method of preparing donor granulocytes for storage, comprising: (a) obtaining donor granulocytes from a suitable donor; (b) isolating said donor granulocytes; (c) contacting said donor granulocytes with a composition comprising an Spi2A polypeptide equivalent; and (d) storing said donor granulocytes, classified in class 435, subclass 325.

Note: This application contains claims, 4 and 199, directed to patentably distinct inventions comprising the following Spi2A polypeptide equivalents:

Serpin B1, Serpin B2, Serpin B3, Serpin B4, Serpin B6, Serpin B8 and Serpin B9

However, each of the specifically Spi2A polypeptide equivalents consisting of specific amino acid sequences recited in the specification on page 22, lines 7-20 lack unity of invention because the amino acid sequences have no substantial structural similarities although they have a common utility, i.e. generation of antibodies. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300(CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Furthermore, there are approximately eight different databases that accompany the results of a search of one discrete amino acid or nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search of two different amino acid sequences, and different amino acid segments in the databases would require extensive searching and review.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed Spi2A polypeptide equivalent for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the invention that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Note: This application contains claims, 6 and 193, directed to patentably distinct inventions comprising the following polypeptides comprising 4 to 8 consecutive amino acid residues of the amino acid sequences MAGVGCCA or FVVAECCM:

However, each of the specifically recited polypeptides having 4 to 8 consecutive amino acid residues of the amino acid sequence of MAGVGCCA or FVVAECCM lack unity of invention because the amino acid sequences have no substantial structural similarities although they have a common utility, i.e. generation of antibodies. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300(CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984).

Furthermore, there are approximately eight different databases that accompany the results of a search of one discrete amino acid or nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search of two different amino acid sequences, and different amino acid segments in the databases would require extensive searching and review.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed amino acid sequence, e.g., MAGVGCCA or FVVAECCM, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the invention that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-XI are related by the virtue that each of the claimed methods use an Spi2A polypeptide. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different

design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, while each of the methods utilize the same Spi2A polypeptide, the subjects to be treated represent separate and distinct populations with different morphologies and functions such that one population could not be interchanged with the other. As such, the instantly claimed methods are not obvious variants because each population would require different searches and the consideration of different patentability issues.

The inventions of Groups XII-XXII are related by the virtue that each of the claimed methods use an Spi2A polypeptide equivalent. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, while each of the methods utilize the same Spi2A polypeptide equivalent, the subjects to be treated represent separate and distinct populations with different morphologies and functions such that one sample population could not be interchanged with the other. As such, the instantly claimed methods are not obvious variants because each population would require different searches and the consideration of different patentability issues.

The inventions of Groups XXIII-XXXIII are related by the virtue that each of the claimed methods use a polypeptide having 4 to 8 consecutive amino acid residues of the amino acid sequence of MAGVGCCA or FVVAECCM. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, while each of the methods utilize the same polypeptide having 4 to 8 consecutive amino acid residues of the amino acid sequence of MAGVGCCA or FVVAECCM, the subjects to be treated represent separate and distinct populations with different morphologies and functions such that one population could not be interchanged with the other. As such, the instantly claimed methods are not obvious variants because each population would require different searches and the consideration of different patentability issues.

The inventions of Groups XXXIV-XXXVI are related by the virtue that each of the claimed methods are used for the preparation of donor granulocytes for storage. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions of Groups XXXIV-XXXVI utilize polypeptides having no substantial structural similarities. As such, the instantly claimed methods have a materially different design.

The inventions of Groups I-XXXIII and XXXIV-XXXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that their methods would be used together. The method for modulating cell death in a cell or patient comprising contacting said cell with an SpiA2 polypeptide or an Spi2A polypeptide equivalent or a polypeptide comprising 4 to 8 consecutive amino acid residues of the amino acid sequences of MAGVGCCA or FVVAECCM and a method of preparing donor granulocytes for storage comprising contacting said donor granulocyte with a composition comprising an SpiA2 polypeptide or an Spi2A polypeptide equivalent or a polypeptide comprising 4 to 8 consecutive amino acid residues of the amino acid sequences of MAGVGCCA or FVVAECCM are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for treatment and preparation differ significantly for each of the materials. Therefore, each method is divergent in materials and steps. For these reasons the inventions of Groups I-XXXIII and XXXIV-XXXVI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups I-XXXIII and XXXIV-XXXVI have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I-XXXIII and XXXIV-XXXVI.

Because the inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER